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Should Acellular Dermal Matrices Be Used for Implant-based Breast Reconstruction after Mastectomy? Clinical Recommendation Based on the GRADE Approach

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Background: Acellular dermal matrices (ADMs) entered the market in the early 2000s and their use has increased thereafter. Several retrospective cohort studies and single surgeon series reported benefits with the use of ADMs. However, robust evidence supporting these advantages is lacking. There is the need to define the role for ADMs in implant-based breast reconstruction (IBBR) after mastectomy.
Methods: A panel of world-renowned breast specialists was convened to evaluate evidence, express personal viewpoints, and establish recommendation for the use of ADMs for subpectoral one-/two-stage IBBR (compared with no ADM use) for adult women undergoing mastectomy for breast cancer treatment or risk reduction using the Grading of Recommendations, Assessment, Development, and Evaluation (GRADE) approach.
Results: Based on the voting outcome, the following recommendation emerged as a consensus statement: the panel members suggest subpectoral one- or two-stage IBBR either with ADMs or without ADMs for adult women undergoing mastectomy for breast cancer treatment or risk reduction (with very low certainty of evidence).
Conclusions: The systematic review has revealed a very low certainty of evidence for most of the important outcomes in ADM-assisted IBBR and the absence of standard tools for evaluating clinical outcomes. Forty-five percent of panel members expressed a conditional recommendation either in favor of or against the use of ADMs in subpectoral one- or two-stages IBBR for adult women undergoing mastectomy for breast cancer treatment or risk reduction. Future subgroup analyses could help identify relevant clinical and pathological factors to select patients for whom one technique could be preferable to another. *(Plast Reconstr Surg Glob Open 2023; 11:e4821; doi: 10.1097/GOX.0000000000004821; Published online 22 February 2023.)*

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INTRODUCTION

Acellular Dermal Matrices for Immediate IBBR

Despite the increased use of oncoplastic breast conserving techniques, mastectomy is still performed in up to 40%–50% of breast cancer patients, with a marked increase in bilateral mastectomy and in the use of the so-called conservative mastectomies over the last two decades.[1,2] Simultaneously, there has been an increase in demand for breast reconstruction, and a significant rise in immediate breast reconstructions.[3]

Acellular dermal matrices (ADMs) entered the market in the early 2000s and their use has increased thereafter.[4] ADMs are used to cover the lower pole of the reconstructed breast and to support the implant during implant-based breast reconstruction (IBBR). ADMs derive from porcine,

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bovine, or human cadaver dermis or pericardium; all cells and antigens are chemically removed from tissues, leaving an ADM.[5] The matrix is then sutured to the distal part of the pectoralis major muscle and possibly to the submammary fold in order to create an "internal bra."[4]

Several retrospective cohort studies and single surgeon series reported benefits with the use of ADM, including a reduced need for tissue expanders, decreased incidence of capsular contracture, and improved aesthetic outcome and cost reduction.[4,6,7]

However, robust evidence supporting these advantages is lacking. Furthermore, data from a systematic review and a recent randomized controlled trial (RCT) have raised concerns regarding higher complication rates associated with the use of ADM in IBBR, such as seroma, infection, skin necrosis, and implant loss.[8,9]

Objectives

The aim of this recommendation is to provide evidence-based indications for the use of ADMs for subpectoral one- or two-stage IBBR. The target audience includes patients and a broad range of healthcare professionals, including (1) breast surgical oncologists and plastic surgeons; (2) radiation and medical oncologists; (3) breast radiologists; (4) psycho-oncologists; (5) patients' advocacy representatives and (6) decision makers. Policy makers could express interest in these guidelines because use of ADMs in IBBR could have a potential impact on healthcare costs, allowing higher rates of direct-to-implant breast reconstructions. In order to evaluate current available evidence on the above mentioned aim and the formulation of a final recommendation, the Grading of Recommendations, Assessment, Development, and Evaluation (GRADE) approach was used.[10]

METHODS

The methods of the GRADE used to assess available evidence and develop our recommendation are reported in Supplemental Digital Content 1. (**See appendix 1, Supplemental Digital Content 1,** which displays the methods used in this study. **http://links.lww.com/PRSGO/C406**.)

RESULTS

Search Strategy Results and Details of the Identified Relevant Studies

The literature search yielded 560 items after elimination of duplicate records. A total of 104 full-text articles were assessed for eligibility, among which 37 studies met pre-defined criteria,[6,9,11–45] with 20 studies included in meta-analyses[9,11–29,46–48] (Fig. 1).

Studies were conducted in the United States, Canada, Peru, the Netherlands, Sweden, United Kingdom, Italy, Switzerland, and Israel with a total of 277,702 patients involved. All studies included patients undergoing subpectoral one or two-stage IBBR after mastectomy with or without the use of ADMs.

Takeaways

Question: Although acellular dermal matrices (ADMs) are widely used worldwide for breast reconstruction after mastectomy, no clear evidence is available to support their use.

Findings: We convened a panel of experts in breast reconstruction worldwide to evaluate the available evidence on ADMs, using the GRADE method. The GRADE revealed a very low certainty of evidence for most of the important outcomes related to the use of ADMs.

Meaning: There is a strong need of better evidence supporting the use of ADMs in breast reconstruction and for selecting patients who could benefit from their use.

Study design included RCTs, prospective cohorts, case-control studies, cross-sectional studies, and database analyses.

The intervention group consisted of both one- and two-stage ADM-assisted IBBR. The comparison group was mostly comprised of standard two-stage breast reconstruction with one study considering one stage IBBR without ADMs.[12] None of the included studies investigated prepectoral implant positioning. (**See appendix 2, Supplemental Digital Content 2,** which displays the main features of the primary studies. **http://links.lww.com/PRSGO/C407**.)

Effects of Intervention

Evidence synthesis and certainty for each of the prioritized outcomes were presented in the evidence profile. (**See appendix 3, Supplemental Digital Content 3**, which displays the prioritized outcome. **http://links.lww.com/PRSGO/C408**.) (**See appendix 4, Supplemental Digital Content 4,** which displays the study results in forest plots. **http://links.lww.com/PRSGO/C409**.) (**See appendix 5, Supplemental Digital Content 5,** which displays the evidence profiles. **http://links.lww.com/PRSGO/C410**.)

Quality of Life

One study reported data on overall quality of life,[20] and it was designed as an RCT, comparing both one- and two-stage IBBR with and without the use of ADM. Quality of life was assessed with BREAST-Q[49] The study included 64 patients in the group with ADM use and 65 patients in the group without ADM use. The mean difference for overall quality of life was 1.00 (95% CI: −2.13 to 4.13) in favor of the use of ADMs (certainty of evidence: very low).

Psychosocial Well-being

A total of four studies reported data on psychosocial well-being[9,14,20,46,47]; two of these[9,20,46] were designed as RCTs and two[14,47] as observational studies. Psychosocial well-being was assessed with BREAST-Q. The RCTs compared both one-stage IBBR with the use of ADMs versus standard two-stage implant-based reconstruction, and two-stage reconstruction with the use of ADMs versus two-stage reconstruction without the use of ADMs, considering a total of 112 patients in the group using ADMs and 109 patients in the group not using ADMs. The mean

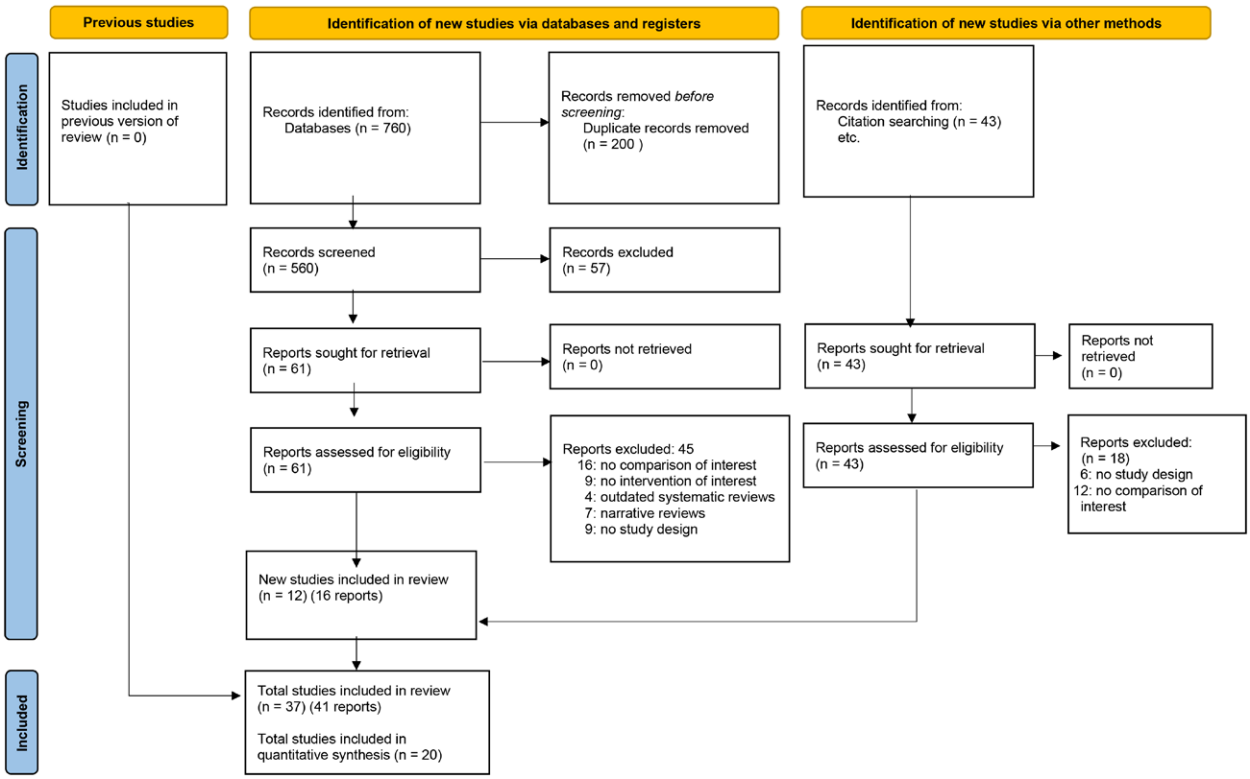

Fig. 1. PRISMA flowchart.

difference for psychosocial well-being assessed in the RCTs was 3.59 (95% CI: −0.93 to 8.12; I^2: 35%) in favor of the use of ADMs (certainty of evidence: low).

The observational studies compared both one- and two-stage IBBR with ADMs versus both one- and two-stage reconstruction without ADMs, including a total of 704 patients in the ADM group and 697 patients in the group without ADMs. The mean difference for psychosocial well-being assessed in the observational studies was 2.95 (95% CI: −0.67 to 6.56, I^2: 20%) in favor of the use of ADMs (certainty of evidence: low).

Physical Well-being

A total of four studies reported data on physical well-being[9,14,20,46,47]; two of these[9,20,46] were designed as RCTs and two[14,47] as observational studies. Physical well-being was assessed with BREAST-Q. The RCTs compared both one-stage and two-stage IBBR with the use of ADMs versus standard two-stage IBBR without the use of ADMs, considering a total of 112 patients in the group with ADMs and 109 patients in the group without ADMs. The mean difference for physical well-being assessed in the RCTs was 1.15 (95% CI: −1.68 to 3.98; I^2: 10%) in favor of the use of ADMs (level of certainty: low).

The observational studies compared both one- and two-stage IBBR with the use of ADMs versus both one- and two-stage reconstruction without the use of ADMs, including a total of 704 patients in the group with ADMs and 697 patients in the group without ADMs. The mean difference for physical well-being assessed in the observational studies was −0.23 (95% CI: −4.04 to 3.58, I^2: 47%) in favor of not using ADMs (certainty of evidence: low).

Satisfaction with Breast

A total of five studies reported data on satisfaction with breasts[9,14,21,22,46,47]; two of these[9,21,46] were designed as RCTs and three[14,22,47] as observational studies. Satisfaction with breasts was assessed with BREAST-Q. The RCTs compared both one-stage and two-stage IBBR with the use of ADMs versus two-stage reconstruction without the use of ADMs, considering a total of 112 patients in the group with the use of ADMs and 108 patients in the group without the use of ADMs. The mean difference for satisfaction with breasts assessed in the RCTs was 4.99 (95% CI: −0.05 to 10.02; I^2: 0%) in favor of the use of ADMs (certainty of evidence: low).

The observational studies compared both one and two-stage IBBR with the use of ADMs versus both one- and two-stage reconstruction without the use of ADMs, considering a total of 723 patients in the group with ADMs and 718 patients in the group without ADMs. The mean difference for satisfaction with breasts assessed in the observational studies was 0.73 (95% CI: −1.12 to 2.58; I^2: 0%) in favor of the use of ADMs (certainty of evidence: low).

Satisfaction with Outcome

A total of two studies reported data on satisfaction with outcome[9,14,46]; one of these[9,46] was designed as an RCT and one[14] as an observational study. Satisfaction with outcome was assessed with BREAST-Q. The RCT compared

one-stage IBBR with the use of ADMs versus standard two-stage IBBR, considering a total of 48 patients in the group with ADMs and 43 patients in the group without ADMs. The mean difference for satisfaction with breasts assessed in the RCT was 5.00 (95% CI: −2.28 to 12.28) in favor of the use of ADMs (certainty of evidence: very low).

The observational study compared both one and two-stage IBBR with the use of ADMs versus both one- and two-stage reconstruction without the use of ADMs, considering a total of 49 patients in the group with ADM and 55 patients in the group without ADM. The mean difference for satisfaction with outcome assessed in the observational study was 0.00 (95% CI: −7.99 to 7.99; certainty of evidence: very low).

Total Surgical Complications

A total of 13 studies reported data on total surgical complications.[9,11–13,15,17,19,24,25,27,28,46–48] Two of these[9,19,46] were designed as RCTs and 11[11–13,15,17,24,25,27,28,47,48] as observational studies. The RCTs compared both one-stage and two-stage IBBR with the use of ADMs versus standard two-stage reconstruction without the use of ADMs, considering a total of 134 patients in the group with ADMs and 143 patients in the group without ADMs. The risk ratio (RR) for total surgical complications assessed in the RCTs was 1.94 (95% CI: 1.18–3.20, I^2: 38%) in favor of not using ADMs (certainty of evidence: low).

The observational studies compared both one- and two-stage IBBR with the use of ADMs versus both one- and two-stage reconstruction without the use of ADMs, considering a total of 3436 patients in the group with ADMs and 9783 patients in the group without ADMs. The RR for total surgical complications assessed in the observational studies was 1.28 (95% CI: 1.10–1.48, I^2: 21%; certainty of evidence: low).

Infections

A total of nine studies reported data on infections[11,12,15,17,19,26,29,47,48]; one of these[19] was designed as an RCT and eight [11,12,15,17,26,29,47,48] as observational studies.

The RCT compared two-stage breast reconstruction with the use of ADMs versus two-stage without the use of ADMs, considering a total of 65 patients in the group with ADMs and 70 patients in the group without ADMs. The RR for infections assessed in the RCTs was 1.08 (95% CI: 0.28–4.13) in favor of not using ADMs (certainty of evidence: low).

The observational studies compared both one- and two-stage IBBR with the use of ADMs versus both one- and two-stage reconstruction without the use of ADMs, including a total of 5605 patients in the group with ADM and 19650 patients in the group without ADM. The odds ratio for infections assessed in the observational studies was 1.21 (95% CI: 1.05–1.39, I^2: 0%; certainty of evidence: low).

Implant Loss

A total of 12 studies reported data on implant loss[9,11,14,16,17,21,23,25,28,46–48]; two of these[9,21,46] were designed as RCTs and nine[11,14,16,17,23,25,28,47,48] as observational studies. The RCTs compared both one- and two-stage IBBR with the use of ADMs versus standard two-stage IBBR without the use of ADMs, including a total of 134 patients in the group with ADMs and 140 patients in the group without ADMs. The RR for implant loss assessed in the RCTs was 3.09 (95% CI: 0.41–23.27, I^2: 71%) in favor of not using ADMs (certainty of evidence: low).

The observational studies compared both one and two-stage IBBR with the use of ADMs versus both one- and two-stage reconstruction without the use of ADMs, including a total of 3650 patients in the group with ADMs and 9842 patients in the group without ADMs. The RR for implant loss assessed in the observational studies was 1.76 (95% CI: 0.91–3.41; I^2: 91%) (certainty of evidence: low).

Re-interventions

A total of six studies reported data on re-interventions[9,11,12,14,18,46,48]; two of these[9,18,46] were designed as RCTs and four[11,12,14,48] as observational studies. The RCTs compared both one- and two-stage IBBR with the use of ADM versus standard two-stage IBBR without the use of ADM, considering a total of 134 patients in the group with ADMs and 143 patients in the group without ADMs. The RR for re-interventions assessed in the RCTs was 1.56 (95% CI: 0.61–4.03; I^2: 85%) in favor of not using ADMs (certainty of evidence: very low).

The observational studies compared both one and two-stage IBBR with the use of ADMs versus both one- and two-stage reconstruction without the use of ADMs, including a total of 1897 patients in the group with ADMs and 7584 patients in the group without ADMs. The RR for re-interventions assessed in the observational studies was 1.05 (95% CI: 0.87–1.28; I^2: 6%; certainty of evidence: low).

Values and Preference, Equity, Acceptability, Feasibility

A summary of evidence and panelists' judgments are presented in the evidence to decision framework. (**See appendix 6, Supplemental Digital Content 6,** which displays the evidence to decision framework. **http://links.lww.com/PRSGO/C411**.)

Resource Use and Cost-effectiveness

Of the panelists, 37.5% considered the cost-effectiveness to favor the use of ADMs in IBBR. (**See appendix 7, Supplemental Digital Content 7,** which displays the cost-effectiveness analysis and economic evaluation. **http://links.lww.com/PRSGO/C412**.)

Recommendation

In the light of summarized judgments for each domain in evidence to decision, panelists were asked to discuss the recommendation for use of ADMs for subpectoral one- or two-stage IBBR for adult women undergoing mastectomy for breast cancer treatment or risk reduction. Forty-five percent of the panelists offered a conditional recommendation for either the intervention or the comparison. The following recommendation emerged: "The panel members suggest subpectoral one- or two-stage IBBR either with ADMs or without ADMs for adult women undergoing mastectomy for breast cancer treatment or risk reduction (with very low certainty of evidence)."

DISCUSSION

The current available evidence on the use of ADMs in subpectoral one- and two-stage IBBR comes mainly from observational studies and one RCT comparing use versus no use of ADMs in two-stage IBBR, observational studies comparing both one- and two-stage ADM-assisted IBBR versus standard one- and two-stage IBBR, and one RCT comparing one-stage ADM-assisted IBBR versus standard two-stage IBBR.

Despite the very low level of evidence shown by most of the studies, the majority of the anticipated benefits for the use of ADMs are not supported by the evidence deriving from the meta-analysis. According to this systematic review of the literature, ADM use is associated with significantly higher rates of surgical complications and infections when compared with no use of ADMs in both one-stage and two-stage subpectoral IBBR. Furthermore, the use of ADMs was not associated with significantly better results in any of the potentially desirable outcomes such as overall quality of life, psycho-social well-being, physical well-being, satisfaction with outcome, and satisfaction with breasts.

The directions of some desirable and undesirable effects with the use of ADMs go to opposite sides, most of the time not being strongly in favor or against the use of ADMs. This is probably the reason why 45% percent of the panel members expressed a conditional recommendation either in favor or against the use of ADMs.

This outcome was predictable because there is no single reconstructive technique that is better than another in absolute terms, underlying the importance of patient selection using factors conferring suitability. Morphovolumetric characteristics of the breast, subcutaneous thickness, and patterns of vascularity should also be preoperatively assessed to identify subgroups that could benefit from one technique more than another.[50]

Several studies have investigated ADM-assisted breast reconstruction, but only a few provided clear indications on the use of these devices, reporting outcomes associated with a selective use.[51,52]

ADMs allow for implant coverage in the presence of an insufficient or compromised pectoralis major muscle and/or serratus fascia. Moreover, ADMs could have a positive impact on the intraoperative fill volume of the tissue expander (in terms of intraoperative and final, more expeditious, complete filling), better definition and control of the inframammary fold and breast lower pole.[15,35–42] However, these potential benefits should be balanced with costs and potentially higher complication rates, as reported by our systematic review.

Jordan et al proposed an algorithm for the selective use of ADMs in two-stage breast reconstruction, considering BMI, breast size, radiation history, and intraoperative factors such as sentinel lymph node biopsy results, pectoralis major integrity/width, and flap vascularity.[51] Their model suggests that a personal history of radiation therapy should be considered as a contraindication to ADM use, but postoperative radiation should not. Additionally, ADMs should not be used on patients with low BMI and small breasts. They also suggest that a positive sentinel lymph node biopsy during intraoperative assessment could be an indication for ADM use (due to the increased likelihood of postmastectomy radiotherapy), but poor flap vascularity should discourage the use of ADMs.

Another algorithm for IBBR has been also proposed,[53] defining indications on the use of ADMs according to clinical factors, such as breast volume, ptosis, and thickness of superficial tissues, according to the breast tissue coverage classification proposed by Rancati et al.[54] The thickness of the superficial tissues at preoperative digital mammography has been demonstrated to be associated with the aesthetic outcome of IBBR.[53,54] Therefore, subgroup analyses would be helpful to identify potential subgroups of patients in whom one technique (ADM use or not) could be preferable to another.

A higher postoperative complication rate in IBBR patients undergoing postmastectomy radiotherapy (PMRT) is reported, irrespective of the use of ADMs, when compared with those not undergoing PMRT.[55] It would be extremely relevant to obtain data from future studies comparing use versus no use of ADMs in patients undergoing PMRT or previously irradiated, in order to assess a possible reduced risk of complications in patients undergoing ADM-assisted IBBR.

Reduced vascularization due to microvascular fibrosis is a known sequela of radiation therapy.[55] Decreased vascularization of the ADMs could preclude its integration, leading to higher risk of complications and reconstruction failure.[55]

Despite a poor level of evidence, no studies have shown a protective effect of ADMs in previously irradiated patients,[35,56,57] but there could be a potential indication for ADM use in patients with anticipated need for PMRT, based on a preoperative evaluation of risk factors and tumor characteristics. In this case the re-vascularization and integration of the ADM could occur before the initiation of the radiation treatment.[57]

In parallel, it would be desirable to obtain data from well-designed comparative studies showing the impact of other variables (BMI, smoking status, personal history of RT, PMRT, pre-operatively assessed thickness of the superficial tissues, and patterns of vascularity, intraoperatively-assessed mastectomy flap thickness) on the outcome of IBBR with or without ADM use. This is of particular importance, as currently some authors[51] advocate for the use of ADMs in patients with high BMI, but others[52] caution their use in morbidly obese patients because the thick subcutaneous tissue could lead to poor adhesion of the ADM, determining a higher risk for complications. Defining the characteristics of patients who could benefit from the use of ADMs would be extremely relevant in order to guide our reconstructive choices and improve the outcomes for our patients. Additional considerations regarding limitations of the study, subgroup analyses, and research priorities are reported in Supplemental Digital Content 8

and 9. (**See appendix 8, Supplemental Digital Content 8,** which displays the additional considerations regarding limitations of the study search strategy. **http://links.lww.com/PRSGO/C413**.) (**See appendix 9, Supplemental Digital Content 9,** which displays the search strategy. **http://links.lww.com/PRSGO/C414**.)

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